Essential Action
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March 21, 2008

Rachel S. Bae
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement

Dear Director Bae,

Essential Action submits the following comments to the Office of the United States Trade Representative (USTR) concerning a proposed Anti-Counterfeiting Trade Agreement (ACTA).

Essential Action is a project of Essential Information, a non-profit 501(c)(3) organization based in Washington, D.C. We are concerned generally with protecting the public domain and the information commons. A key organizational area of focus is promoting access to medicines, including in the United States and especially in developing countries. While we recognize that many other important issues are implicated by the proposed treaty, our comments focus particularly on concerns about the proposed ACTA in the context of the public health priority of ensuring access to safe and affordable medicines to patients around the world, regardless of income or wealth.

ACTA priorities

USTR's fact sheet and ACTA materials conflate patent, copyright and trademark infringement, "piracy" and counterfeiting. An agreement based on, or reflecting, such a conflation of distinct concepts is likely to be overly broad, proscribing behavior that cannot correctly be identified as counterfeiting and that is not necessarily detrimental to the public interest. For example, commercially interested parties sometimes cast compulsory licensing for medicines -- legal under national legislation and World Trade Organization rules -- as patent theft or "piracy," but no one can argue these practices bear any resemblance to counterfeiting. At the same time, an agreement focused on patent, copyright and trademark infringement is likely to overlook important options to control counterfeiting, including by requiring companies to disclose knowledge of counterfeit products.

A multilateral counterfeiting treaty should concern itself specifically and uniquely with the dangers and harms posed to the public by counterfeit goods. Paramount among these

it "is not accessible to the WHO, health authorities or the public."[2] Industry groups seem to favor general public awareness of the counterfeiting problem, which may lead to public assistance in enforcement, but sometimes disfavor public knowledge of specific counterfeited products.

For example, in 1995, GlaxoSmithKline allegedly asked the Ghanaian government not to alert the public of the presence of fake halofantrine antimalarial syrup in the market, for the sake of the company's reputation.[3] In 2002 in Kansas City, BMS and Eli Lilly settled for $72 million with the families of deceased victims of counterfeit drugs, seemingly to avoid the precedent that drug companies could be held liable for failing to disseminate information about counterfeits.[4]

Governments should require companies to disclose any information they obtain about the existence of dangerous counterfeit products. If the public is to incur expenses combating counterfeiting, the public should at least have a right to the best information available so its enforcement activities are effective. We are concerned that proposals for mandatory disclosure requirements are absent from the available materials on the ACTA.

There are at least two existing proposals for statutory disclosure requirements. Cockburn *et al.* propose a model based on the United Kingdom Civil Aviation Authority's reporting requirements for suspected unapproved aircraft parts.[5] Companies would be required to report suspected counterfeits to regulatory agencies. The agency would then take responsibility for confirming the report and deciding whether and when to alert law enforcement and the public. Meanwhile, legislation introduced by Representative Steve Israel (2nd District of New York) proposed requiring drug companies to notify the FDA within two days of learning of a counterfeit threat.[6]

Enforcement practices: public/private advisory groups

USTR's ACTA fact sheet mentions provisions for advisory groups assisting in enforcement practices. It is important that any such advisory groups consist of balanced memberships representing not only industry, but also consumers, and, in the case of medicines, generics firms as well as brand-name companies. Overrepresentation of patent, copyright and trademark-dependent industries in anti-counterfeiting enforcement

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[2] "The global threat of counterfeit drugs: why industry and governments must communicate the dangers." Robert Cockburn, Paul N. Newton, E. Kyerematen Agyarko, Dora Akunyili, Nicholas J. White, Public Library of Science (PLoS) Medicine, April 2005, Volume 2, Issue 4, at 305.

[3] BUKO, *supra*, and PLoS, *supra*. GlaxoSmithKline also was reluctant to share information about fake syrup with the authors of the PLoS article.

[4] PLoS, *supra*. There are, of course, counterexamples. "In 2002, Johnson and Johnson issued 200,000 letters to health care professionals in the US warning them of fake Procrit…within one week of being notified of a severe counterfeit problem." PLoS.

[5] PLoS, *supra* at 307.

[6] H.R. 2345, 109th Congress.

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